UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 05, 2022

SAB BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39871**	**85-3899721**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2100 East 54th Street North Sioux Falls, South Dakota	**57104**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 605 679-6980

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	SABS	The NASDAQ Stock Market LLC
Warrants, each exercisable for one share of Common Stock at an exercise price of $11.50 per share	SABSW	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On July 5, 2022, SAB Biotherapeutics, Inc. (the “Company” or “SAB”) made available a new corporate strategy presentation (the "Presentation") on the Investor Relations section of the Company’s website. A copy of the Presentation is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The foregoing (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and will not be deemed to be filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise be subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act. The information contained in the Presentation is summary information that should be considered in the context of the Company’s filings with the Securities and Exchange Commission and other public announcements the Company may make by press release or otherwise from time to time.

Cautionary Note Regarding Forward-Looking Statements

Certain statements made in this Current Report on Form 8-K and the Presentation that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding future events, including the development and efficacy of SAB-195 (C. Diff), SAB-176 (Influenza), SAB-142 (Type 1 Diabetes & Immunology), SAB-185 (COVID-19), and our other discovery programs; our cash runway into 2023; and potential future government and third-party collaborations or funded programs. These statements are based on the current expectations of SAB and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on, by any investor as a guarantee, an assurance, a prediction or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict, may differ from assumptions, and are beyond the control of SAB. A further description of risks and uncertainties can be found in the sections entitled “Risk Factors” in SAB’s most recent Annual Report on Form 10-K, most recent quarterly reports on Form 10-Q, and in other filings SAB makes with the Securities and Exchange Commission, available at https://www.sec.gov/. Except as otherwise required by law, SAB disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The exhibits listed on the Exhibit Index are incorporated herein by reference.

Exhibit Number	Description
99.1	Presentation dated July 5, 2022.
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SAB Biotherapeutics, Inc.

Date: July 5, 2022

By: */s/ Eddie J. Sullivan*
Eddie J. Sullivan
Chief Executive Officer

EXHIBIT 99.1

SAb BIOTHERAPEUTICS

ADVANCING POWERFUL NEW CLASS OF IMMUNOTHERAPEUTIC ANTIBODIES

July 2022

Forward Looking Statements

The material in this presentation has been prepared by SAB Biotherapeutics, Inc. ("SAB") and is general background information about SAB's activities current as of the date of this presentation. This information is given in summary form and is not intended to be complete. Information in this presentation, including financial forecasts, should not be considered advice or a recommendation to investors or potential investors in relation to holding, purchasing or selling securities or other financial products or instruments and does not take into account any particular investment objectives, financial situation or needs.

This presentation may contain forward looking statements including statements regarding our intent, belief or current expectations with respect to SAB's businesses and operations, market conditions, results of operations and financial condition, capital adequacy, specific provisions and risk management practices. Readers are cautioned not to place undue reliance on these forward-looking statements. SAB does not undertake any obligation to update any information herein for any reason or to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof to reflect the occurrence of unanticipated events unless required by law. While due care has been used in the preparation of forecast information, actual results may vary in a materially positive or negative manner and the presentation may contain errors or omissions. Forecasts and hypothetical examples are subject to uncertainty and contingencies outside SAB's control. Past performance is not a reliable indication of future performance. The forward looking statements contained or implied in this presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in SAB's most recent Annual Report on Form 10-K with the Securities and Exchange Commission (the "SEC") and in other filings that SAB makes with the SEC.

Unless otherwise specified, information is current at the date hereof.

Experienced Management Team

Samuel J. Reich
EXECUTIVE CHAIRMAN, BOD
- 20 years Biopharma Executive and BOD
- Bioentrepreneur
- Co-founder Acuity Pharmaceuticals, OPKO Health, Biscayne Neurotherapeutics
- Molecular Biologist, Inventor, former PENN

Eddie J. Sullivan, PhD
PRESIDENT & CEO / CO-FOUNDER
- 20 years new technology development
- 25+ years biotech
- Former Japanese pharma
- BIO Executive Committee
- Reproductive physiologist

Russell Beyer, MBA, CMA
CHIEF FINANCIAL OFFICER
- 25+ years Pharma & Fortune 100
- Country/region CFO at AstraZeneca, Clorox
- Track record of driving growth, integrations
- Strategic financial, operations, reporting, planning

Christoph Bausch, PhD, MBA
CHIEF OPERATING OFFICER
- 15+ years platform technology commercialization
- Sigma Aldrich
- Stowers Institute Postdoc

Alexandra Kropotova, MD
CHIEF MEDICAL OFFICER
- 20+ years global clinical development
- Biopharmaceutical R&D leader, Pfizer, Wyeth, Sanofi, Teva Specialty R&D
- Board member, iBio
- Contributed to numerous patents & compounds leading portfolios from Phase I to BLA and NDA approvals

Novel DiversitAb™ Platform for Developing Highly-Differentiated Immunotherapies

SAb BIOTHERAPEUTICS

Robust, growing clinical-stage pipeline spanning multiple therapeutic areas

Vertical integration enables rapid, scalable development of multi-targeted products

Leveraged advanced genetic engineering & antibody science to develop Tc bovine-derived fully-human polyclonal antibodies

Established proof-of-concept through US Government funded programs & partnerships totaling ~$200MM

Strong corporate position with experienced leadership team and growing infrastructure

Innovative DiversitAb™ platform produces a new class of targeted fully-human, highly-potent polyclonal antibodies

Versatile Antibody Platform with Ability to Capture Multiple Markets

Human Antibody Discovery & Development Engine, New Source for IgG, Therapeutic Production Represents Multibillion-Dollar Market Opportunity

Polyclonal Antibody Development	–Fully human, targeted, high-potency –Multivalent, multi-targeted	• **Robust pipeline across multiple therapeutic areas** • **Potential to capture mAb, hIVIG, animal pAb markets and address unmet needs**
Human Immunoglobulin	–Specifically targeted –Large-scale, consistent, managed donor pool, genetically representing single human donor	• ***In vivo* data demonstrating comparability to approved SC product and potential benefits over human-derived**
Monoclonal Antibody Discovery	–Larger volume of antibodies –Greater diversity; higher affinity –Robust (ruminant) immune response	• **Multiple ongoing global pharma collaborations**

Multi-Pronged Business Strategy Powered by Novel Proprietary Platform

Opportunity to Create New Class of Immunotherapies

DiversitAb Platform

- **RAPID PROOF-OF-CONCEPT** (90 days to CGMP)
- **NATURAL HUMAN ANTIBODIES** (without human donors or serum)
- **MULTI-VALENT CAPABILITIES** (by nature, & by design–multiple targets in one product)
- **TARGET AGNOSTIC** (virus, bacteria, toxin, allergen)
- **SCALABLE, REPLICABLE, CONSISTENT PRODUCTION**

Product Development of Pipeline Assets:
Best-in-Class, First-in-Class & Unmet Needs

- Demonstrated clinical safety and efficacy
- Proof-of-platform with highly-mutating infectious disease
- Robust pipeline with broad therapeutic reach

Industry Partnering & Research Collaborations:
Monoclonal Discovery & Polyclonal Development/Production

- Multiple ongoing collaborations with global pharma
- Opportunities in monoclonal discovery, human immune globulins and therapeutic innovation

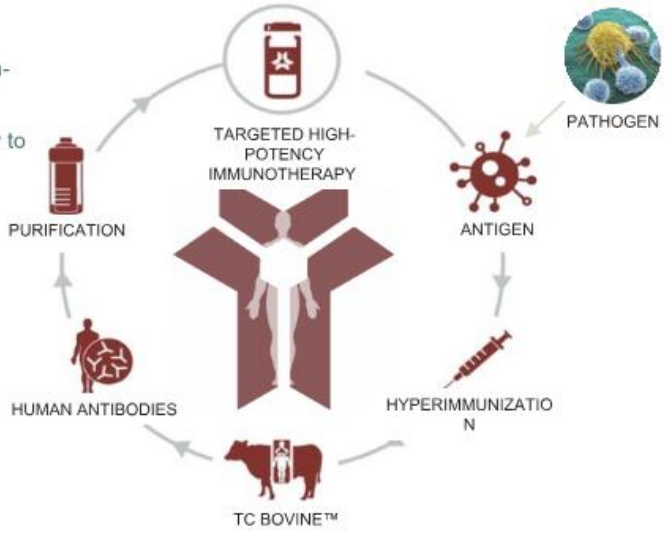
US Gov. Rapid Response Biodefense & Public Health Security:
Emerging Infectious Disease & Biothreats

- $200M awarded for rapid & pandemic response
- Recognized as only therapeutic platform to address priority pathogens by World Health Organization
- Demonstrated *in vivo* efficacy to >12 targets

DiversitAb™ Platform

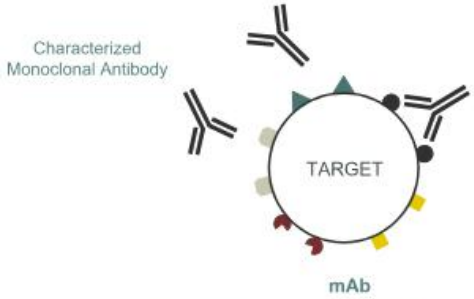
Advancing a new class of fully-human polyclonal Tc bovine-derived antibodies without the need for human serum

- Reliable, controlled, consistent production of diverse, high-titer, high-avidity, fully-human polyclonal antibodies
- Generated antibodies behave similarly to human-derived with ability to specifically target
- Proprietary immunization strategies and robust immune response drive extremely high potency
- Well-established and understood regulatory path as biologic through FDA-CBER
- Vertical integration enabling rapid, scalable development and production of multivalent products



Polyclonals: Broader Spectrum Efficacy Valuable in Range of Indications

FDA: CENTER FOR **DRUG** EVALUATION & RESEARCH (CDER)

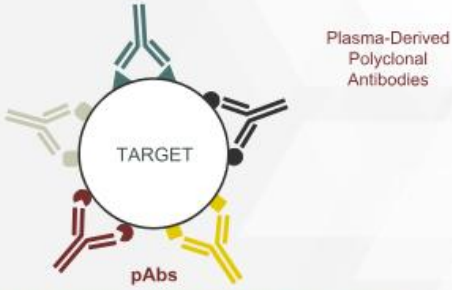


Clones of a single antibody bind to a specific epitope

Monoclonal Approach

- Highly-targeted with specific activity
- Iterative Ab identification and selection process
- Selected and cloned *in vitro*
- May promote escape mutants via selective pressure
- Resistance may develop as pathogen/target mutates
- Current cocktail trend to address resistance

FDA: CENTER FOR **BIOLOGICS** EVALUATION & RESEARCH (CBER)



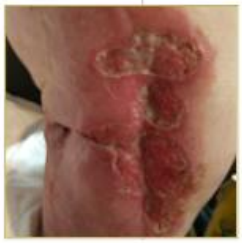
Natural mixture of many antibodies bind to multiple epitopes

Polyclonal Approach

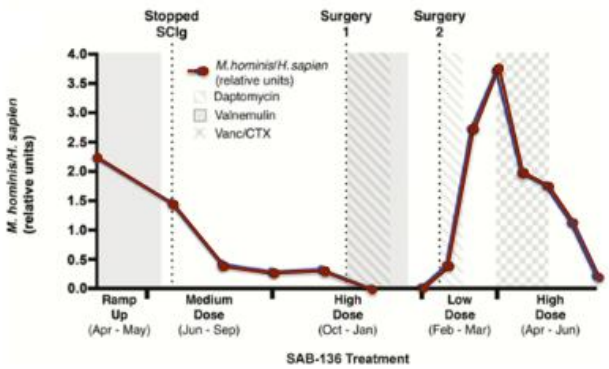
- Diversity of antibodies with multiple modalities
- Naturally selected and produced *in vivo*
- Effective against escape mutants
- Reduced possibility of resistance
- Activates cellular immunity
- Synergistic properties not duplicated by mono- or oligoclonals

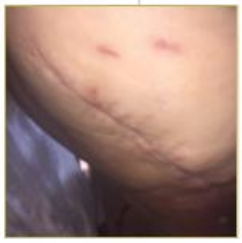
Demonstrated Human Safety and Efficacy in Multi-Dosing Regimen

High-dose therapy resulted in improved clinical parameters associated with reduced *M. hominis* burden following two subsequent infections



Open wound persisted ~7 years prior to treatment





Same area following treatment with SAB -136

BRIGHAM AND WOMEN'S HOSPITAL

HARVARD MEDICAL SCHOOL

JARED N SILVER, CAMERON D ASHBAUGH, JACOB J MILES, HUA WU, GREGORY T MARECKI, JOYCE K HWANG, JIN-AN JIAO, MARK ABRAMS, EDDIE J SULLIVAN, DUANE R WESEMANN, DEPLOYMENT OF TRANSCHROMOSOMAL BOVINE FOR PERSONALIZED ANTIMICROBIAL THERAPY, CLINICAL INFECTIOUS DISEASES, VOLUME 66, ISSUE 7, 1 APRIL 2018, PAGES 1116–1119

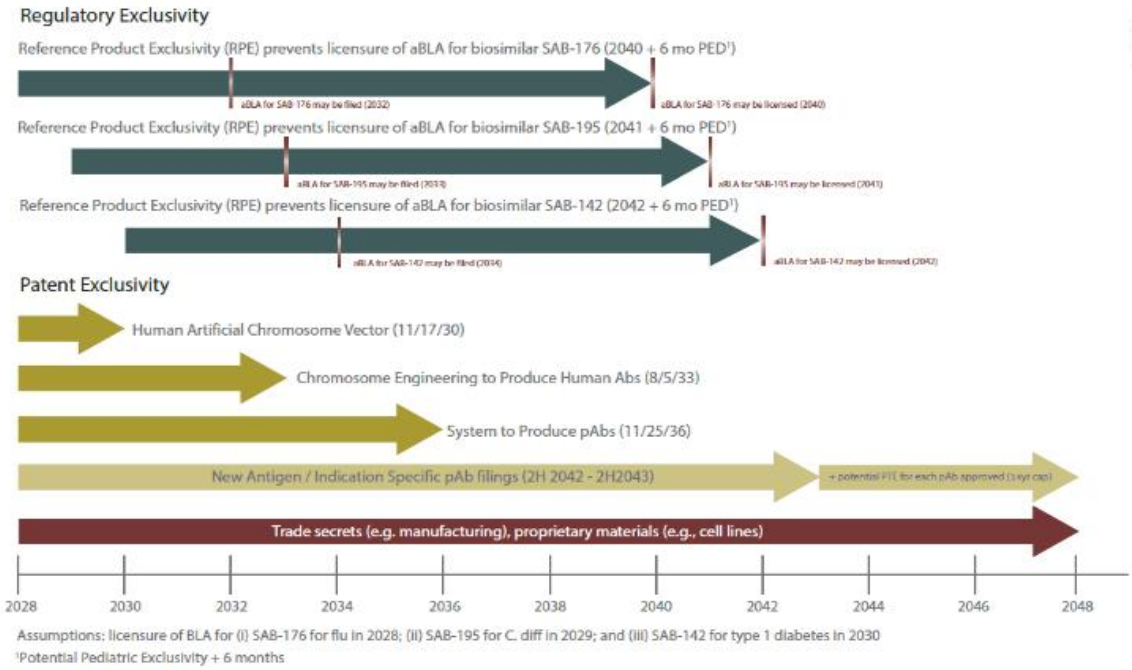
DiversitAb™ Platform is Clinically Validated Across Several Targets

3INDs & 1 CTA	Filed in US and ex-US
7 Clinical Trials	Span from Phase 1 to Phase 3 across 3 indications
Public Collaborations	DoD, BARDA, NIH NIAID, Naval Medical Research Center, USAMRIID
Academic Collaborations	Brigham and Women's Hospital, Harvard, University of South Dakota, University of Pittsburgh

Referenced Trials:

- Safety, Tolerability, and Pharmacokinetics of SAB-176 in Healthy Participants – Full Text View - ClinicalTrials.gov
- Study of SAB-176 in Healthy Adult Participants - Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-185 in Healthy Participants – Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-185 in Ambulatory Participants With COVID-19 - Full Text View - ClinicalTrials.gov
- ACTIV-2: A Study for Outpatients With COVID-19 - Full Text View - ClinicalTrials.gov
- Safety, Tolerability, and Pharmacokinetics of SAB-301 in Healthy Adults – Full Text View - ClinicalTrials.gov

Intellectual Property

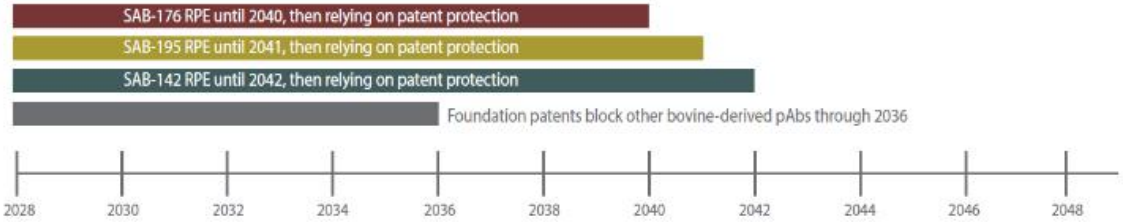


Assumptions: licensure of BLA for (i) SAB-176 for flu in 2028; (ii) SAB-195 for C. diff in 2029; and (iii) SAB-142 for type 1 diabetes in 2030

[1]Potential Pediatric Exclusivity + 6 months

Intellectual Property

Reference Product Exclusivity (RPE) for 12 years from approval of SAb's pAb, FDA may not approve an aBLA for a biosimilar



- Composition of matter / method of use patent protection likely to be available for each of SAb's pAb- for 20 years from filing of application
  - Focus on SAb's pAb and other pAbs (with structural modifications) that would not have any clinically meaningful difference in terms of safety, purity and potency
  - Focus on CDR 1, 2 and 3 of the V_H and V_L chains of key Abs in mixture
- Trade Secrets - numerous trade secrets can last in perpetuity; in process of cataloging and prioritizing
- Any FTO concerns mitigated by launch date & patents often being limited to sequence specific claims

Scaled Infrastructure & Capacity: Tc Bovine & Plasma Production Facility







Scaled Infrastructure & Capacity: Laboratory & Manufacturing


Plasma Purification Suite (50L)


Manufacturing Facility (200L)


Fill Suite


Labeling Suite


Cell Culture Lab


50L Suite


CET Lab

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SELECTED PIPELINE PROGRAMS

Robust Biologic Pipeline with Broad Polyclonal Therapeutic Reach

Ongoing discovery programs in oncology, autoimmune, infectious and anti-idiotype diseases

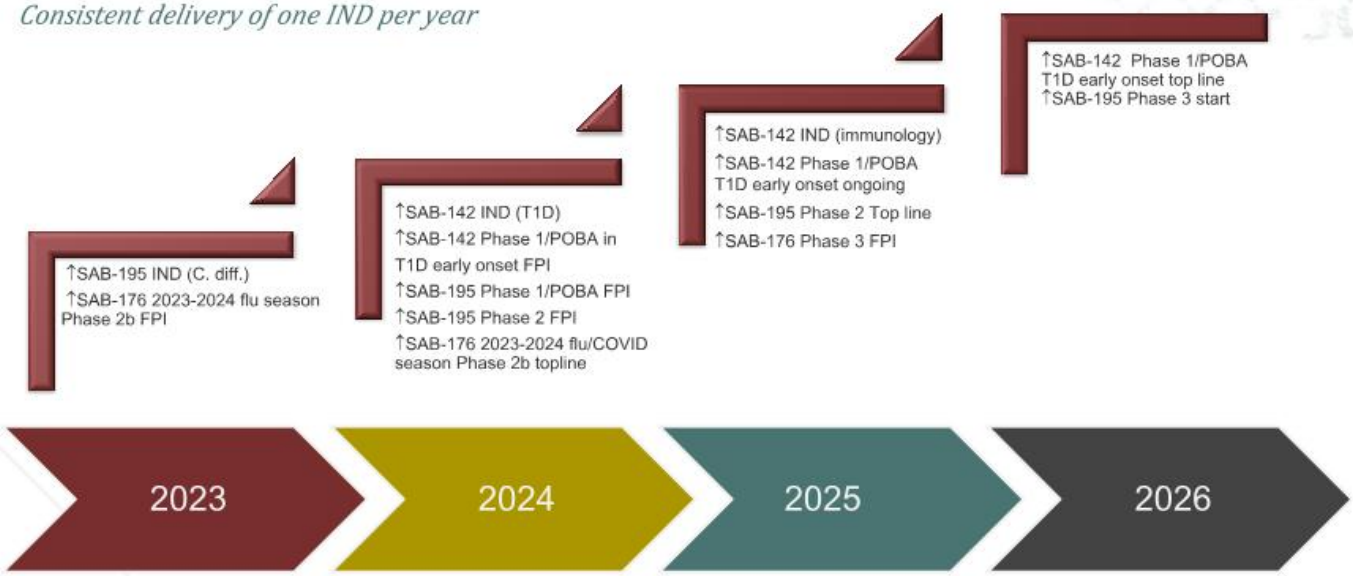
	PRODUCT	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL
GASTROINTESTINAL	SAB-195	CLOSTRIDIOIDES DIFFICILE						
RESPIRATORY	SAB-176	SEASONAL INFLUENZA	Phase 1 Trial & Phase 2a Challenge Study Top line results available					
IMMUNOLOGY	SAB-142	TYPE 1 DIABETES						
	SAB-142	IMMUNOLOGY						

Government-funded Phase 3 clinical-stage program

RESPIRATORY	SAB-185	COVID-19	Phase 3 Trial (NIH ACTIV-2)					

Clinical Development Programs: Focus on the Next 4+ Years

Consistent delivery of one IND per year



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SAB-195:
Clostridioides difficile Infections - Fast to Proof of Concept Option

High Unmet Medical Needs Remain

High Morbidity, Mortality, and Costs

Clostridioides difficile Infection (CDI or C. diff.) is a bacterial infection of the large intestine (colon). A spectrum of clinical disease ranges from mild diarrhea to severe. CDI is characterized by abdominal pain, fever, diarrhea, nausea, and vomiting. Complications of severe CDI include kidney failure, toxic megacolon, bowel perforation, and death.

- CDI infection is one of the most prevalent health care–associated bacterial infections in the US and developed world
  - ~ 500,000 infections per year in the US[1]
  - ~ 30,000 death in the US[1]
- CDI infection is associated with significant costs: Up to $4.8 billion each year in excess health care costs for acute care facilities alone[1]
- Patients with the first CDI recurrence have a risk of subsequent recurrence from 25% to 40% and higher[1, 2]
- CDI-attributable median length of stay and costs (in US$) increased from 7 (4-13) days and $13,168 ($7,525-$24,456) for patients with primary CDI only to 15 (8-25) days and $28,218 ($15,050-$47,030) for patients with recurrent CDI[2]
- The risk of death for patients with recurrent CDI is 33% higher compared to those patients without recurrence

References:
1. CDC. Atlanta, GA: U.S. Department of Health and Human Services. Accessed 6/27/2022 Nearly half a million Americans suffered from Clostridium difficile infections in a single year | CDC Online Newsroom | CDC
2. Economic burden of primary compared with recurrent Clostridium difficile infection in hospitalized patients: a prospective cohort study . J Hosp Infection. 2016 Jul;93(3):286-9

Value Proposition: SAB-195

First in class fully human polyclonal antibody treatment with dual mechanism of action designed to treat severe CDI and reduce CDI recurrence in high-risk patients

Key Differentiators

First in class fully human polyclonal antibody treatment

Only treatment with dual mode of action:

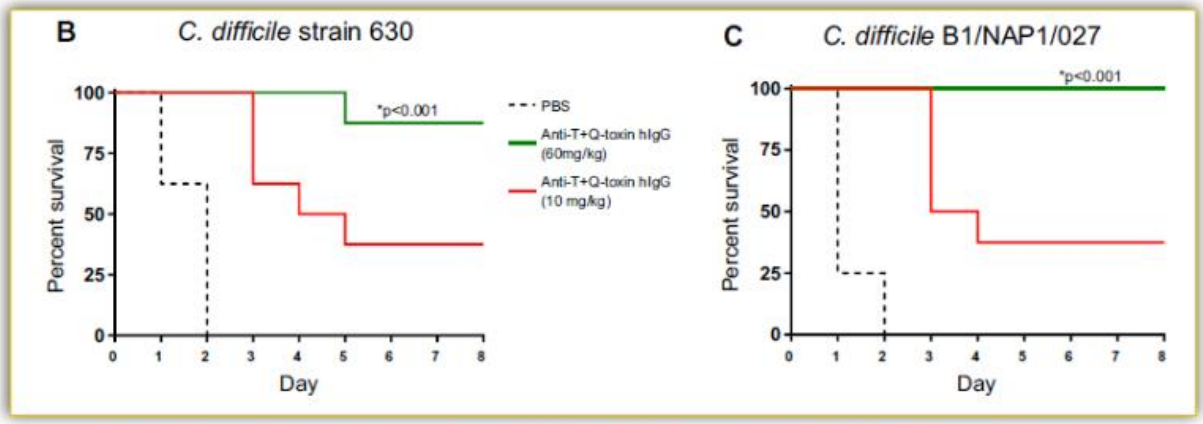
- Unlike bezlotoxumab, SAB-195 targets surface antigen on C. difficile as well as multiple toxins
- Unlike antibiotics, SAB-195 targets several C. difficile toxins responsible for severity of the disease

SAB-195 is target-specific treatment targeting only C. difficile while fully preserving good microbiome

Preclinical data supports potential for competitive efficacy as first-line pAb therapy for severe CDI in patients who are at high risk for CDI recurrences

SAB-195 Preclinical Data

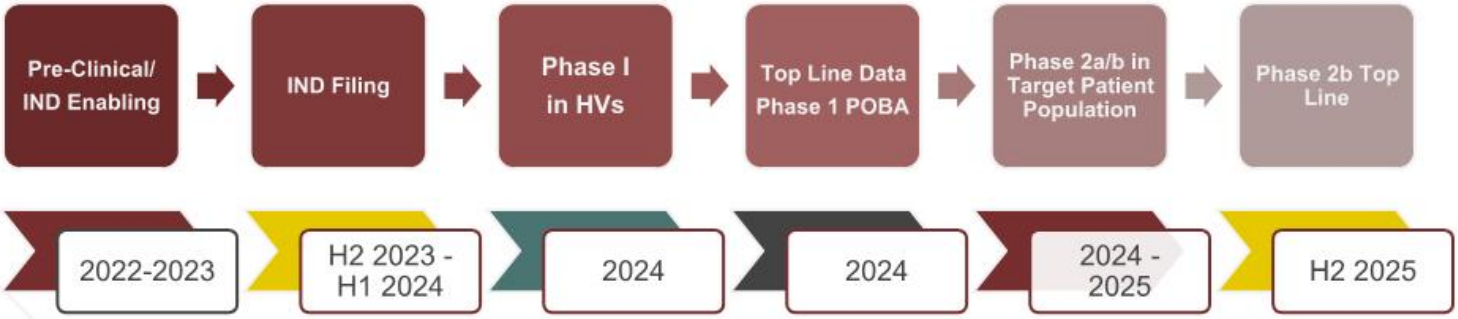
Tc bovine Immunized with Antigen Fusion Proteins Constructed from RBD of TcdA,TcdB(630), TcdB(027) and CDT



Tc bovine-derived anti-quadrivalent toxin hIgG provided 90% to 100% protection in hamsters against C. difficile strain 630 or more virulent epidemic strain NAP1

- Clostridium difficile chimeric toxin receptor binding domain vaccine induced protection against different strains in active and passive challenge models.. Jing-Hui Tian a, Gregory Glenn a, David Flyer a, Bin Zhou a, Ye Liu a, Eddie Sullivan b, Hua Wub, James F. Cummings a, Larry Ellingsworth a,†, Gale Smith
- https://pubmed.ncbi.nlm.nih.gov/28669616/#:~:text=Vaccine,33)%3A4079%2D4087

SAB-195 Development Timelines



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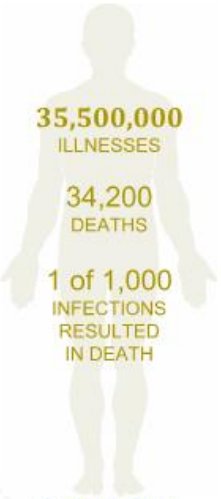
SAB-176:
First In Class Biologic Anti-Influenza Treatment

Unmet Need of Seasonal Influenza



CDC; 2018-19 FLU SEASON

Devastating health and economic impacts

- Estimated 30,000 - 50,000 deaths/year U.S. with 290,000 - 650,000 globally
- ~500,000 hospitalizations annually in U.S.
- Average US hospital stay: $8,000 - $9,000/day; 4-8 days/stay
- Often 30% - 70% failure rate for vaccine; vaccine ineffective in at-risk sub-populations

No current effective treatment for seasonal influenza

- Current antiviral has a 48-hour window
- Approved antiviral small molecule treatments may shorten duration of fever and symptoms, but not effective against clinically meaningful endpoints or neuraminidase mutation; limited efficacious window

Value Proposition: SAB-176

First in class fully human polyclonal antibody treatment aimed to provide superior long-lasting efficacy for prophylaxis and management of influenza in patients at high risk

Key Differentiators

First and only biologic for management of influenza in high-risk patients

Adaptive and cross-reactive to multiple influenza strains

Fully human pAbs uniquely positioned to manage influenza course in high-risk patients including but not limited to:

- Immunocompromised
- Immunosenescent patients
- Patients in long-term care facilities

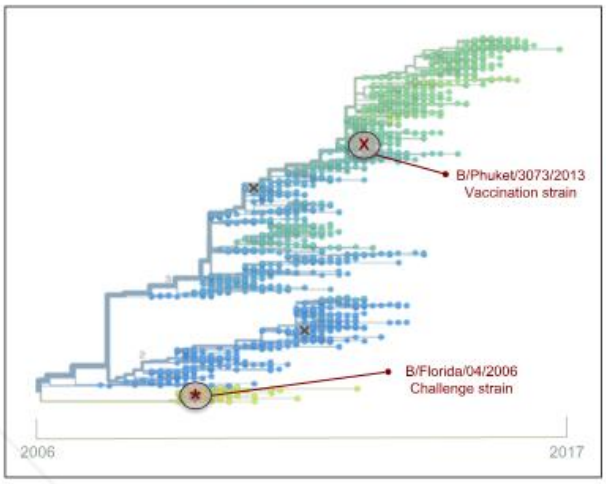
Established Proof of Concept in the well-established validated influenza challenge model

Efficacy Against Mutational Drift

Adaptive & Cross Reactive to Mutating Strains

Highly-Mutational Influenza Virus

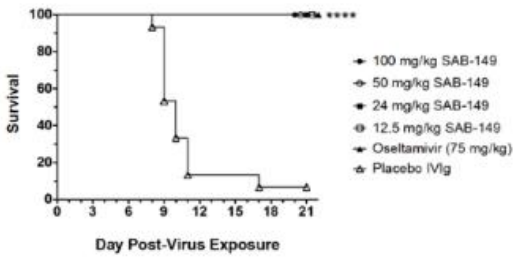
BYAM PHYLOGENIC TREE



SOURCE: NEXTFLU AT HTTPS://NEXTFLU.ORG/VIC/12Y/

100% Protection at All Dose Levels in Influenza Mouse Challenge

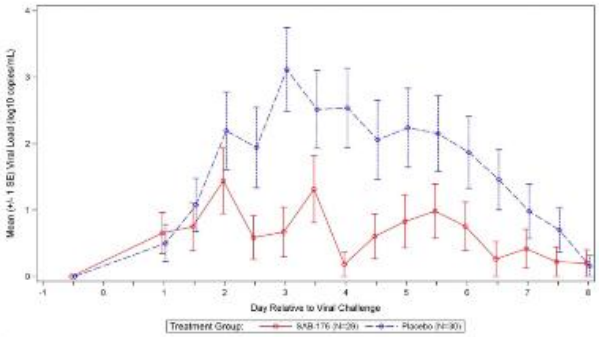
Antibodies produced to **B/Phuket/3073/2013** protected against **B/Florida/04/2006**



Established Proof of Concept for SAB-176:
Met Primary Endpoint of Viral Load Reduction in Phase 2a Challenge Study

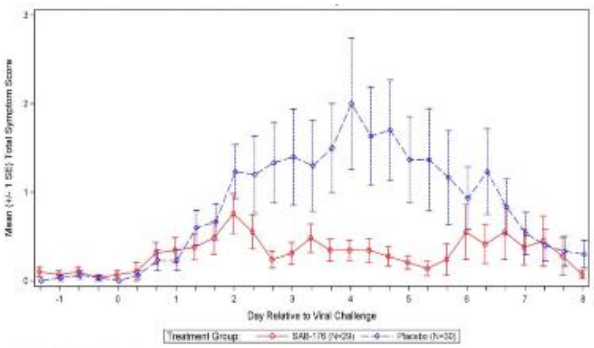
Achieved Statistically Significant (p = 0.026) Reduction in Viral Load

Mean Viral Load by Nasal Samples qRT-qPCR by Day Relative to Viral Challenge



SAB-176 Achieved Statistically Significant (p = 0.013) Improvement in Symptomology at Day 4

Mean Total Symptom Score by Day Relative to Viral Challenge



SAB-176 not specifically targeted to pH1N1 strain used in challenge study

Statistically significant reduction in virus load confirms high cross reactivity to pandemic strain (not targeted with immunogen)

Reinforces ability to generate broadly neutralizing antibodies to viral variants

SAB-176: Clinical Development Plan

	Phase 1: Healthy Volunteers	Planned Phase 2a Challenge Study: Healthy Volunteers	Planned Phase 2b and Phase 3 Designs	
STUDY DESIGN	• Randomized, double-blind, placebo-controlled • 27 healthy volunteers • Single ascending dose study • 1, 10, 25 and 50 mg/kg	• 60 total participants • 60 randomized to SAB-176 or control (30-30) • Challenge strain: H1N1 California (pandemic)	• 300-600 participants • High-risk of serious influenza with symptoms < 4 days • SAB-176 and SOC vs SOC • Dose ranging	• ~1,000 participants (TBD) • High-risk of serious influenza with symptoms ≤ 3-4 days • SAB-176 and SOC vs SOC
ENDPOINTS	• Primary: safety • Secondary: pharmacokinetics, pharmacodynamics, anti-drug antibodies	• Primary: safety and viral load reduction • Secondary: sign/symptom reduction	• Primary: time to onset of clinically significant influenza • Reduction of risk developing influenza symptoms	• Primary: hospitalization and ICU days and death • Secondary: multiple
TIMING	• All participants reached end-of-study • Data being analyzed for final report • Readout expected mid-2021	• Study start 2Q2021 • Readout reported 4Q2021	• Multi-site: Northern hemisphere and/or Southern hemisphere	• Multi-site: Northern hemisphere and/or Southern hemisphere

SAB-176 Development Timelines

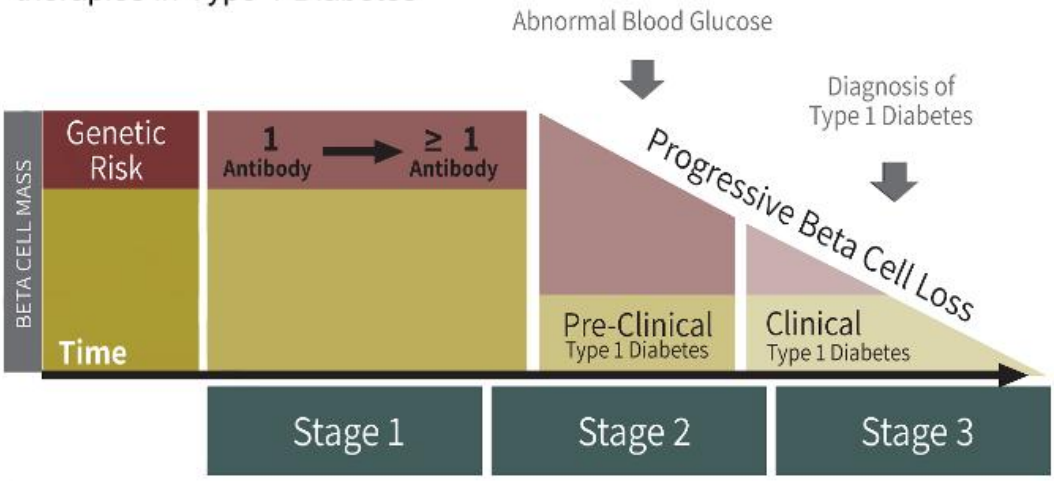
SAb BIOTHERAPEUTICS

SAB-142:
Asset with a Multi-Indication Potential

Type 1 Diabetes

High Unmet Medical Needs Drive High Level of Competition

- Disease-modifying treatments in late-stage development:
  - >100 active interventional trials with small molecules, biologics, and cell therapies in Type 1 Diabetes



Value Proposition: SAB-142

First in class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 T1D

Key Differentiators

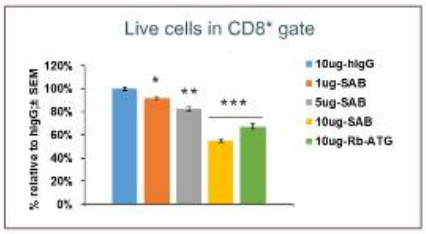
First in class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 T1D

Validated Mechanism of Action by a 3rd party ATG demonstrating reduction in decline in C-peptide vs. placebo (Haller, 2019)

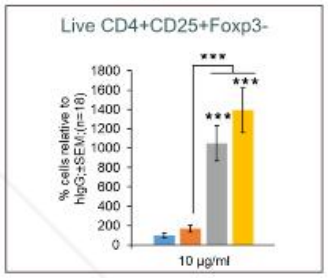
SAB-142: Similar Activity to Approved Rabbit ATG Targets CD8 and Protects T-Regulatory Cells

SAb BIOTHERAPEUTICS

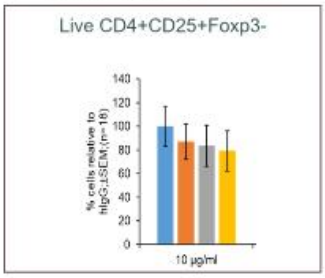
CD8 T Cells



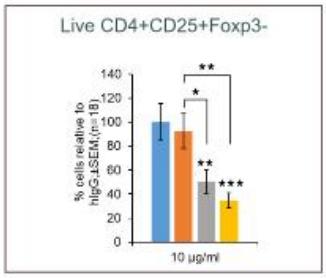
Treg Cells



Activated CD4 T Cells



Naïve CD4 T Cells



SAB-142 Pre-clinical Data Continued

Major subsets of peripheral blood lymphocytes

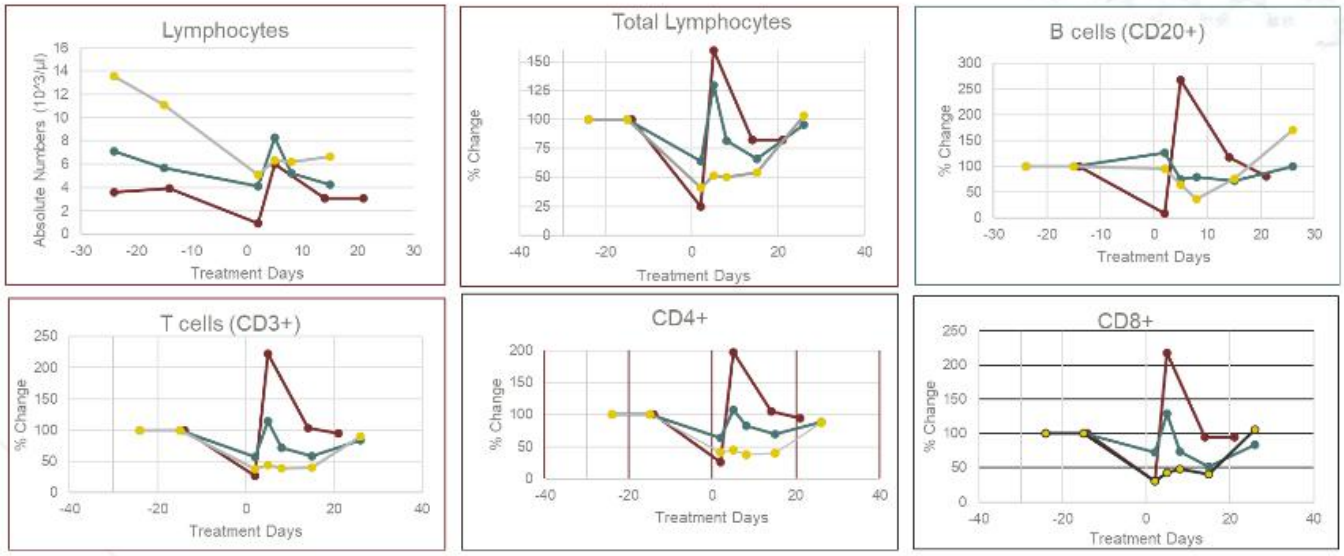
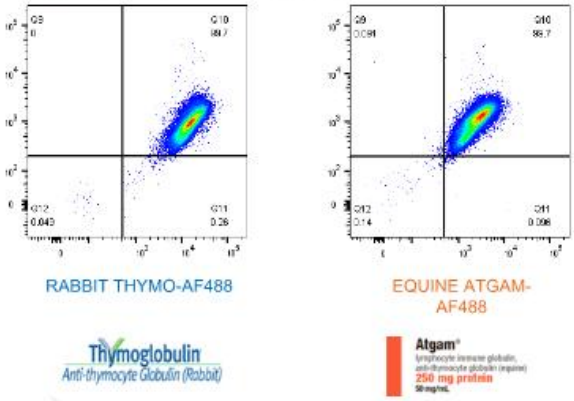


Figure. Changes in major subsets of peripheral blood lymphocytes (total lymphocytes. T and B cells, CD4+ and CD8+ T helpers and killers, respectively) following SAB-142 and ATG treatments. **Red: 5 mg/kg ATG; Blue: 1 mg/kg SAB-142; Grey: 5 mg/kg SAB-142**

SAB-142: MoA Clinically Validated by 3rd Party Compound

2 Years: Low-Dose ATG Preserved C-Peptide in New Onset T1D*

Tc Bovine Human-PB, Rabbit THYMO-AF488, Equine ATGAM-AF488 and Anti-CD3-APC



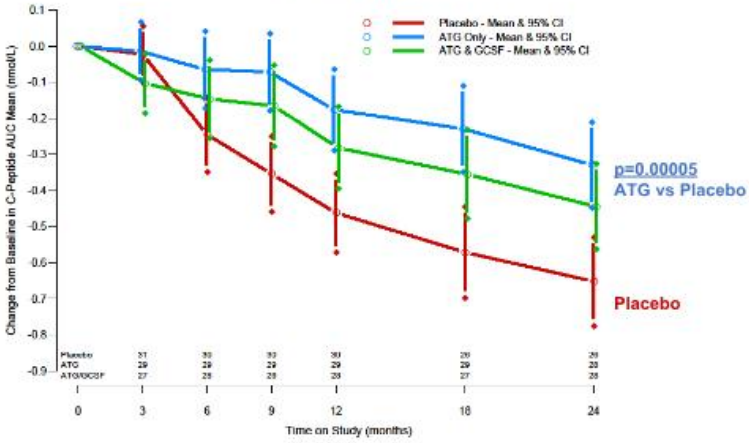
RABBIT THYMO-AF488

EQUINE ATGAM-AF488

Thymoglobulin
Anti-thymocyte Globulin (Rabbit)

Atgam®
250 mg protein

Decline in C-Peptide AUC Mean Over Time by Treatment Group



p=0.00005
ATG vs Placebo

Placebo

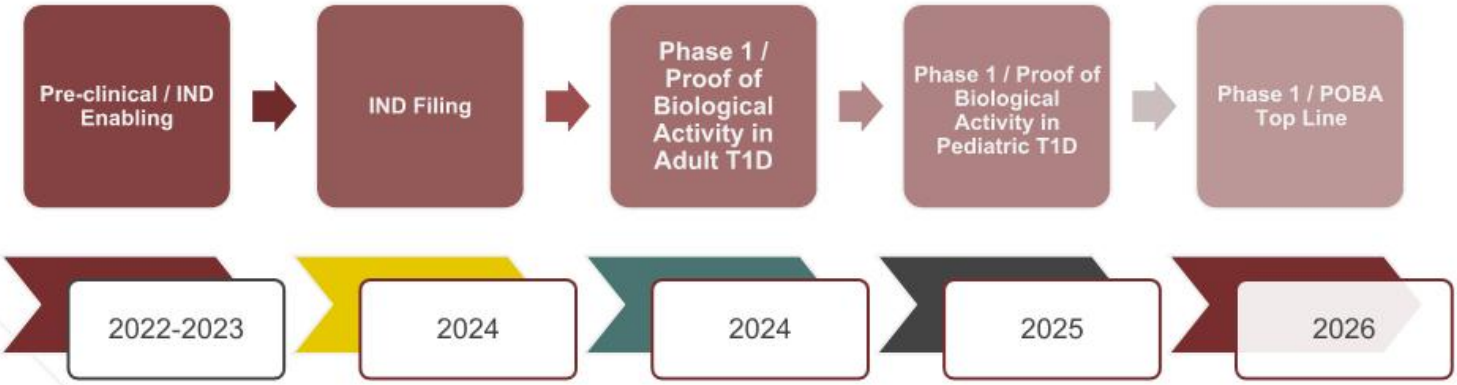
*RABBIT ATG FROM SANOFI – NOT SAB-142 (HUMAN TC-BOVINE DERIVED ATG)

Haller et al. Diabetes. 2019. June, 68(6): 1267-1276

SAB-142: Clinical Development Plan T1D

	Phase 1-2: Early Onset T1D in Adults, followed by adults and adolescents at C-peptide interim analysis	**Phase 3**: New and Recent Onset T1D in Adults and Children (Study 1) At Risk Adults and Children (Study 2)
STUDY DESIGN	• Open-label • Teplizumab or ATG more likely to be a control • XX participants • Ascending dose SAB-142 study • XXX mg/kg (pre-clinical NHP data will adjust) • Biomarker-driven escalation with adaptive randomization based on Safety + CD4, CD8+ cells and Tregs	• Randomized, blinded, PBO and teplizumab controlled • 90 (45:45), a control is either ATG or teplizumab • SAB-142 vs ATG/ teplizumab
ENDPOINTS	• Primary: acute and long-term safety • Primary POBA: C-peptide • Secondary: pharmacokinetics, pharmacodynamics, hypersensitivity (ADA), C-protein, HbA1c, T regs, CD3, CD8/CD4 and other markers.	**New and Recent Onset T1D in Adults and Children (Study 1):** • Primary: improvement/control of TID disease • Secondary: safety, pharmacokinetics, pharmacodynamics, hypersensitivity and serum sickness (ADA), C-protein, HbA1c, CD3, CD8/CD4 and other markers. **At Risk Adults and Children (study 2):** • Primary: time to onset of clinical stage (Stage 3) T1D • Secondary: safety, pharmacokinetics, pharmacodynamics, hypersensitivity and serum sickness (ADA), C-protein, HbA1c, CD3, CD8/CD4 and other markers.

SAB-142 Development Timelines



Summary

- **Executive Management:** Proven team with biotech startup, rapid drug development, and entrepreneurial experience.
- **Platform:** Innovative DiversitAb™ platform produces a new class of targeted fully-human, highly-potent polyclonal antibodies, with a broad efficacy spectrum in a broad range of indications.
- **SAB-195:** Preclinical data supports potential for competitive efficacy as first-line pAb therapy for severe CDI in patients who are at a high risk for recurrences, expect to file IND in 2H 2022.
- **SAB-176:** First in class fully human polyclonal antibody treatment aimed to provide superior efficacy for prophylaxis and management of influenza in patients at high risk, planned initiation of Phase 2b trial in 2H 2023.
- **SAB-142:** First in class fully human polyclonal antibody treatment aimed to provide superior efficacy for delaying onset of clinical Stage 3 Type 1 Diabetes, IND submission expected in 2024.